APR 12 2007

SECTION V
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew EndoButton Fixation Device

Date Prepared: January 16, 2007

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover MA, 01810

B. Company Contact

Deana Boushell

Principle Regulatory Affairs Specialist

Phone: (508) 337-4036

FAX: (508) 261-3620

C. Device Name

Trade Name:	Smith & Nephew EndoButton Direct
Common Name:	Fastener, Fixation, Soft Tissue
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue

D. Predicate Devices

The Smith & Nephew EndoButton Direct is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: The Smith & Nephew EndoButton (K922559).

E. Description of Device

The EndoButton Direct is a machined titanium implant designed to provide cortical fixation in the repair of tendons and ligaments. The design of the EndoButton Direct allows for the device to be endoscopically delivered from a

single access point. The device is available in 5-10mm lengths to accommodate different graft sizes.

F. Intended Use

The Smith & Nephew EndoButton Direct is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) or Posterior Cruciate Ligament (PCL) Reconstruction.

G. Comparison of Technological Characteristics

The Smith & Nephew EndoButton Direct is substantially equivalent in design, materials, function and intended use to the Smith & Nephew EndoButton. The proposed and the predicate devices both have the same intended use, are manufactured from the same material and are offered in a similar size range.

H. Summary Performance Data

The performance testing conducted demonstrates substantial equivalence to the Smith & Nephew EndoButton CL, cleared in K980155 . The testing also demonstrates that the differences in the new device and the predicate device do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
Endoscopy Division
% Ms. Deana Boushell
Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

APR 12 2007

Re: K070167
Trade/Device Name: Smith & Nephew EndoButton Direct
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: January 16, 2007
Received: January 18, 2007

Dear Ms. Boushell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

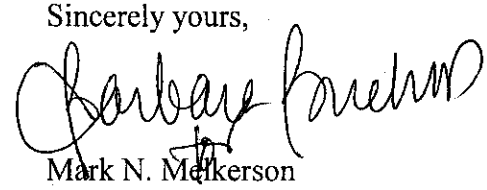
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

§I.D

Indications for Use

510(k) Number (if known): K070167

Device Name: Smith & Nephew EndoButton Direct

Indications For Use:

The Smith & Nephew EndoButton Direct Fixation Device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) or Posterior Cruciate Ligament (PCL) Reconstruction.

Prescription Use ___x_____ AND/OR Over-The-Counter Use No

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070167